

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

DMB

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**Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Dental Products Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 6, 2000, 8:30 a.m. to 5:30 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person:* Pamela D. Scott, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

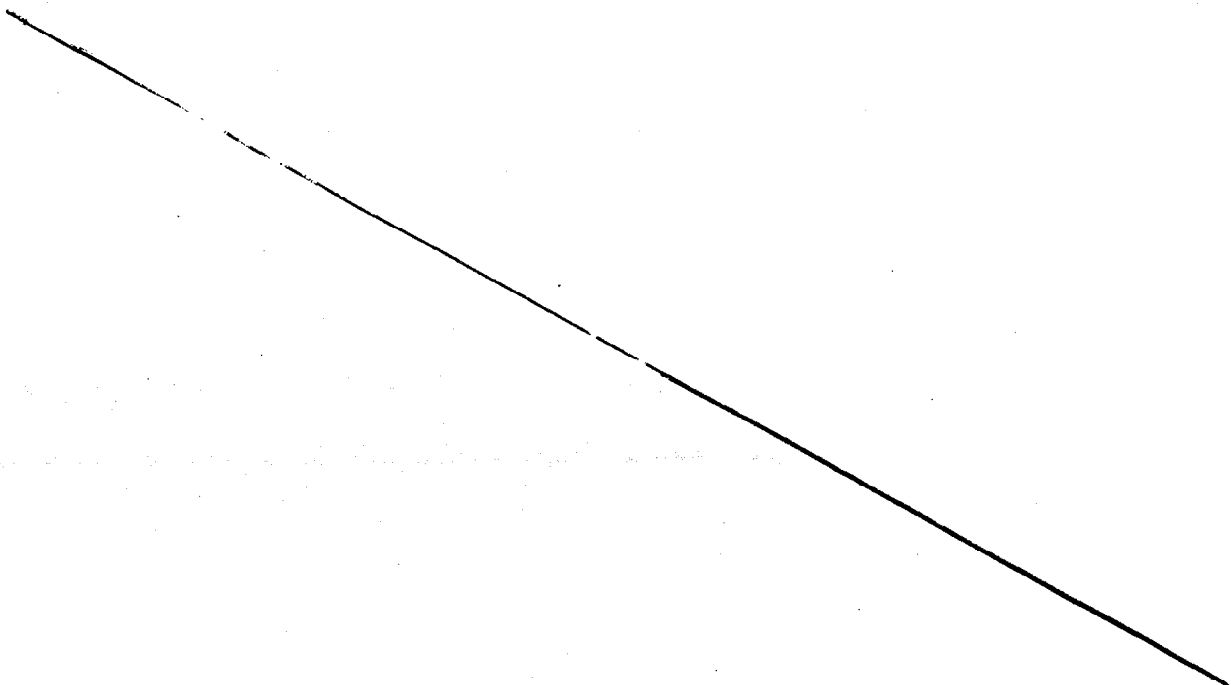
*Agenda:* The committee will discuss, make recommendations, and vote on a premarket approval application for a glenoid fossa prosthesis that is used alone to reconstruct the temporomandibular joint (TMJ). The committee will also discuss and make recommendations on the labeling for a total TMJ prosthesis.

*Procedure:* On October 6, 2000, from 9 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 28, 2000. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and

9:45 a.m. on October 6, 2000. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 28, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On October 6, 2000, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding dental device issues.

FDA regrets that it was unable to publish this notice 15 days prior to the October 6, 2000, Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 20 Sept 00  
September 20, 2000

BA Schwetz

Bernard A. Schwetz

Acting Deputy Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Jan Windsor